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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,782	11/16/2007	Gaetano T. Montelione	RUT0002-00US	1781

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EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
10/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,782	MONTELIONE ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *5-7,10 and 13-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 8, 9, 11, and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-4, 8, 9, 11, and 12 wherein NS1 is protein of Influenza A) in the reply filed on 09/24/2008 is acknowledged.

Claims 5-7, 10, 13-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Non-elected Groups. Election was made **without** traverse in the reply filed on 09/24/2008.

Applicant is reminded to cancel the claims to the non elected Group(s).

Information Disclosure Statement

The references cited in the Search Report 07/30/2007 have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 8, 9, 11-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wang et al (Virology, 1996, Vol. 223, pp 41-50).

Wang et al taught NS1 domain of influenza A and it's binding to dsRNA (see the abstract). In addition, they taught labeled fusion protein to NS1 (see page 42, right column, last full paragraph).

Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Still further, the fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention. See, Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004).

Moreover, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in

fact inherent in the prior art reference. See, Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Still further, Wang et al taught a 55 base pair dsRNA (see page 44). However, the invention as a whole is prima facie obvious, because the Applicants' own disclosure in page 21 lines 28 to 29 asserts "the Length and ribonucleotide sequence of the dsRNA are not critical." Applicants go on to assert that the invention may be conducted using short synthetic dsRNA. Thus, one of ordinary skill in the art at the time of filing would have been motivated by teaching of Wang et al to utilize the binding assay for drug discovery. Especially given Applicants' own admission in the disclosure that the size of the dsRNA is not critical. Therefore, given the teaching of the prior art one of ordinary skill in the art at the time of filing would not have anticipated any unexpected results. Applicants are reminded that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See KSR Int'l Co. v. Teleflex Inc., 550 U.S. (2007). Thus, the invention as a whole is deemed prima facie obvious absent any unexpected results.

Claims 1-4, 8, 9, 11-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over LU et al (Virology, 1995, Vol. 214, pp 222-228)

Lu et al taught NS1 binding to dsRNA (see the abstract). In addition, they taught labeled fusion protein to NS1 (see Figure 1).

Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or

substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Still further, the fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention. See, Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004).

Moreover, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. See, Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

LU et al taught a 29 base pair dsRNA (see page 223). However, the invention as a whole is prima facie obvious, because the Applicants' own disclosure in page 21 lines 28 to 29 asserts "the Length and ribonucleotide sequence of the dsRNA are not critical." Applicants go on to assert that the invention may be conducted using short synthetic dsRNA. Thus, one of ordinary skill in the art at the time of filing would have been motivated by teaching of LU et al to utilize the binding assay for drug discovery. Especially given Applicants' own admission in the disclosure that the size of the dsRNA is not critical. Therefore, given the teaching of the prior art one of ordinary skill in the art at the time of filing would not have anticipated any unexpected results. Applicants are reminded that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See KSR Int'l Co. v. Teleflex Inc., 550 U.S. (2007). Thus, the invention as a whole is deemed prima facie obvious absent any unexpected results.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/A R Salimi/
Primary Examiner, Art Unit 1648

10/14/2008